JENSEN DENTAL

K111743

SEP 14 2011

Section E 510(k) SUMMARY

Submitted by: Jensen Industries
50 Stillman Road
North Haven CT 06473
(203) 239-2090 phone
(203) 234-7630 fax
Contact: Gary Phelps

Date Prepared: June 14, 2011

Device Name: The InSync Ceramic System
Common Name: Dental Porcelain
Classification Name: Porcelain powder for clinical use (21 CFR 872.6660)
Classification: Class II
Product Code: EIH

Predicate Devices: Ceramics 2in1: 510(k) number K043221
Willi Geller Creation CP - ZI: 510(k) number K070114

Device Description

The ***InSync Ceramic System*** consists of pressable silica based ceramic pellets and silica based ceramic layering porcelain and liquids.

Indications for use

The pressable ceramic pellets are pressed onto zirconia frames by dental technicians to fabricate full ceramic crowns and the ceramic layering porcelain and liquids are used to build up the pressed ceramic to final tooth morphology and shade. The ceramic layering porcelain and liquids are also used in building ceramic crowns and bridges on titanium and titanium alloy substructures. Both applications are to provise protheses for missing / damaged teeth.

Comparison to predicate devices

Data has been presented to demonstrate that the respective composition, mechanical properties, chemical qualities, and the indications for use make the ***InSync Ceramic System*** substantially equivalent to the predicate devices ***Willi Geller Creation CP-Zi*** and ***Ceramics 2in1*** porcelains. The safety and effectiveness of the ***InSync Ceramic System***, being determined by the shared chemical qualities and mechanical properties, is therefore equivalent to the predicate devices. Independantly, the ***InSync Ceramic System*** meets the applicable sections of concensus standards ISO 9693 and ISO 6872.

JENSEN DENTAL 50 Stillman Road, North Haven, CT 06473
(800) 243-2000 (203) 239-2090 (203) 239-7630 Fax www.jensendental.com

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Gary Phelps
Quality Assurance Manager
Jensen Industries, Incorporated
50 Stillman Road
North Haven, Connecticut 06473

SEP 14 2011

Re: K111743
Trade/Device Name: The InSync Ceramic System
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Code: EIH
Dated: June 06, 2011
Received: June 21, 2011

Dear Mr. Phelps:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111743

Device Name: The InSync Ceramic System

Indications for Use: The pressable ceramic pellets are pressed onto zirconia frames by dental technicians to fabricate full ceramic crowns and the ceramic layering porcelain and liquids are used to build up the pressed ceramic to final tooth morphology and shade. The ceramic layering porcelain and liquids are also used in building ceramic crowns and bridges on titanium and titanium alloy substructures. Both applications are to provise protheses for missing / damaged teeth.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K111743